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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
ODLAND, KATHRYN P	

ART UNIT	PAPER NUMBER
3743	18

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,464	LLANOS ET AL.	
	Examiner	Art Unit	
	Kathryn Odland	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10,12,13,15-17 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10, 12, 13, 15-17, and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated August 29, 2003. Claims 1-8, 10, 12, 13, 15-17, and 52 are pending.

Response to Arguments

1. Applicant's arguments with respect to claims 1 and 52 have been considered but are moot in view of the new ground(s) of rejection. The new limitations change the scope of the claim and thus a new ground(s) of rejection has been applied.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-8 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Chudzik et al. in US 2002/0041899.

Regarding claim 1, Chudzik et al. disclose a local drug delivery apparatus having a medical device for implantation into a treatment site of a living organism, as recited in section [0002]; a first layer including at least one agent in therapeutic

dosages incorporated in a polymeric matrix and affixed to the medical device for the treatment of reactions by the living organism caused by the medical device or implantation thereof, as recited in section [0022]; and a second layer including a lubricious material for preventing the at least one agent from separating from the medical device prior to implantation of the medical device at the treatment site, the second layer including a lubricious material being affixed to the at least one of the medical device or a delivery system for the medical device, as recited in section [0080].

Regarding claim 2, Chudzik et al. disclose that as applied to claim 1, as well as, a medical device that is an intraluminal medical device, as recited in sections [0065]-[0071].

Regarding claim 3, Chudzik et al. disclose that as applied to claim 2, as well as, an intraluminal device that is a stent, as recited in sections [0065]-[0071].

Regarding claim 4, Chudzik et al. disclose that as applied to claim 1, as well as, the at least one agent that is an anti-proliferative, as recited in sections [0054]-[0063].

Regarding claim 5, Chudzik et al. disclose that as applied to claim 1, as well as, the at least one agent that is an anti-inflammatory, as recited in sections [0054]-[0063].

Regarding claim 6, Chudzik et al. disclose that as applied to claim 1, as well as, the at least one agent that is an anti-coagulant, as recited in section [0054]-[0063].

Regarding claim 7, Chudzik et al. disclose that as applied to claim 1, as well as, the at least one agent that is an immunosuppressant, as recited in sections [0054]-[0063].

Regarding claim 8, Chudzik et al. disclose that as applied to claim 1, as well as, the at least one agent that is a non-viral gene introducer, as recited in sections [0054]-[0063].

Regarding claim 10, Chudzik et al. disclose that as applied to claim 1, as well as, the lubricious coating that is incorporated onto the medical device, as recited in section [0080].

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chudzik in US 2002/0041899 in view of Sydney et al. in US Patent No. 6,306,144 or Opolski in US Patent No. 5,272,012.

Regarding claim 12, Chudzik et al. disclose that as applied to claim 1. However, Chudzik et al. do not explicitly recite a lubricious coating that is incorporated onto the delivery system for the medical device. On the other hand, stents are typically deployed via a catheter based system and both Sydney et al. and Opolski teach lubricious coatings on catheter delivery systems, as discussed throughout the specifications and abstracts. Therefore, it would be obvious to modify the invention of Chudzik et al. to assure the delivery system also has a lubricious coating for the purpose of a smooth delivery where the coatings remain on the apparatus during delivery as taught by both Sydney et al. and Opolski.

Regarding claim 13, Chudzik et al. disclose that as applied to claim 1. However Chudzik et al. do not explicitly recite a lubricious coating that is a silicone-based material. On the other hand, both Sydney et al. and Opolski teach a lubricious

coating that is a silicone-based material, as discussed throughout the specifications and abstracts. Therefore, it would be obvious to modify the invention of Chudzik et al. to assure the lubricant is a silicone-based material, as taught by both Sydney et al. and Opolski for the purpose of its superior qualities and a lubricant.

6. Claims 15-17 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chudzik et al. in US 2002/0041899.

Regarding claim 52, Chudzik et al. disclose a local drug delivery apparatus having a medical device for implantation into a treatment site of a mixing organism, as recited in section [0002]; a first layer including at least one agent in therapeutic dosages incorporated in a polymeric matrix and affixed to the medical device for the treatment of reactions by the living organism caused by the medical device or implantation thereof, as recited in section [0022]; and a second layer including a coating for preventing the at least one agent from separating from the medical device prior to implantation of the medical device at the treatment site, the coating material being affixed to the at least one of the medical device or a delivery system from the medical device, as recited in section [0080]. However, Chudzik et al. do not explicitly recite a second layer that has a water soluble powder for preventing separation. On the other hand, a water soluble powder is within the scope of that discussed in section [0080] and it

would be obvious to one with ordinary skill in the art to have the lubricant be a water soluble powder according to the method of coating and well within the scope of the invention.

Regarding claim 15, Chudzik et al. as modified disclose that as applied to claim 52, as well as, a water soluble powder that is incorporated onto the medical device, as recited in section [0080].

Regarding claim 16, Chudzik et al. as modified disclose that as applied to claim 15, as well as, a water soluble powder that is an anti-oxidant, as recited in sections [0054]-[0063].

Regarding claim 17, Chudzik et al. as modified disclose that as applied to claim 15, as well as, a water soluble powder that has an anti-coagulant, as recited in sections [0054]-[0063].

7. Claims 1-8, 10, 12, 13, 15-17, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chudzik et al. in US Patent No. 6,214,901 in view of Sydney et al. in US Patent No/ 6,306,144 or Opolski in US Patent No. 5,272,012.

Regarding claim 1, Chudzik et al. disclose a local drug delivery apparatus having a medical device for implantation into a treatment site of a living organism, as

recited in column 3 and column 5, lines 28-67and a first layer including at least one agent in therapeutic dosages incorporated in a polymeric matrix and affixed to the medical device for the treatment of reactions by the living organism caused by the medical device or implantation thereof, as recited in columns 3-5. However, Chudzik et al. do not explicitly recite a second layer including a lubricious material for preventing the at least one agent from separating from the medical device prior to implantation of the medical device at the treatment site, the second layer including a lubricious material being affixed to the at least one of the medical device or a delivery system for the medical device. On the other hand, stents are typically deployed via a catheter based system and both Sydney et al. and Opolski teach lubricious coatings on catheter delivery systems, as discussed throughout the specifications and abstracts. Therefore, it would be obvious to modify the invention of Chudzik et al. to assure the delivery system also has a lubricious coating for the purpose of a smooth delivery where the coatings remain on the apparatus during delivery as taught by both Sydney et al. and Opolski.

Regarding claim 2, Chudzik et al. as modified disclose that as applied to claim 1, as well as, a medical device that is an intraluminal medical device, as recited in column 5.

Regarding claim 3, Chudzik et al. as modified disclose that as applied to claim 2, as well as, an intraluminal device that is a stent, as recited in column 5.

Regarding claim 4, Chudzik et al. as modified disclose that as applied to claim 1, as well as, the at least one agent that is an anti-proliferative, as recited in column 5, etc.

Regarding claim 5, Chudzik et al. as modified disclose that as applied to claim 1, as well as, the at least one agent that is an anti-inflammatory, as recited in column 5.

Regarding claim 6, Chudzik et al. as modified disclose that as applied to claim 1, as well as, the at least one agent that is an anti-coagulant, as recited in column 5.

Regarding claim 7, Chudzik et al. as modified disclose that as applied to claim 1, as well as, the at least one agent that is an immunosuppressant, as recited in column 5.

Regarding claim 8, Chudzik et al. as modified disclose that as applied to claim 1, as well as, the at least one agent that is a non-viral gene introducer, as recited in column 5.

Regarding claim 10, Chudzik et al. as modified disclose that as applied to claim 1, and it would be further obvious to one with ordinary skill in the art to have the lubricious coating is incorporated onto the medical device for the purpose of preventing dissociation from the device prior to insertion.

Regarding claim 12, Chudzik et al. as modified disclose that as applied to claim 1, as well as a lubricious coating that is incorporated onto the delivery system for the medical device.

Regarding claim 13, Chudzik et al. as modified disclose that as applied to claim 1. Further, both Sydney et al. and Opolski teach a lubricious coating that is a silicone-based material, as discussed throughout the specifications and abstracts. Therefore, it would be obvious to modify the invention of Chudzik et al. to assure the lubricant is a silicone-based material, as taught by both Sydney et al. and Opolski for the purpose of its superior qualities and a lubricant.

Regarding claim 52, Chudzik et al. disclose a local drug delivery apparatus having a medical device for implantation into a treatment site of a mixing organism, as recited column 5 and a first layer including at least one agent in therapeutic dosages incorporated in a polymeric matrix and affixed to the medical device for the treatment of reactions by the living organism caused by the

medical device or implantation thereof, as recited in columns 3-5, etc. However, Chudzik et al. do not explicitly recite a second layer including a water soluble powder for preventing the at least one agent from separating from the medical device prior to implantation of the medical device at the treatment site, the second layer including a water soluble material being affixed to the at least one of the medical device or a delivery system from the medical device. . On the other hand, stents are typically deployed via a catheter based system and both Sydney et al. and Opolski teach lubricious coatings on catheter delivery systems, as discussed throughout the specifications and abstracts. Therefore, it would be obvious to modify the invention of Chudzik et al. to assure the delivery system also has a lubricious coating for the purpose of a smooth delivery where the coatings remain on the apparatus during delivery as taught by both Sydney et al. and Opolski. Further, a water soluble powder is within the scope of lubricious coatings and it would be obvious to one with ordinary skill in the art to have the lubricant be a water soluble powder according to the method of coating and well within the scope of the invention.

Regarding claim 15, Chudzik et al. as modified disclose that as applied to claim 52, and it would be further obvious to one with ordinary skill in the art to have the lubricious coating is incorporated onto the medical device for the purpose of preventing dissociation from the device prior to insertion.

Regarding claim 16, Chudzik et al. as modified disclose that as applied to claim 15, and it would be further obvious and within the scope of the invention as modified to have the water soluble powder have/be is an anti-oxidant.

Regarding claim 17, Chudzik et al. as modified disclose that as applied to claim 15, and it would be further obvious and within the scope of the invention as modified to have the water soluble powder have/be an anti-coagulant.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 6,254,634 and US Patent No. 6,179,817.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

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